IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM; and TISSUEGEN, INC., *Plaintiffs,* *v.* BOSTON SCIENTIFIC CORP., *Defendant.*	CASE NO. 1:17-cv-01103 JURY TRIAL DEMANDED

PLAINTIFFS' ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiffs BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM ("UT") and TISSUEGEN, INC. ("TissueGen") (collectively, "Plaintiffs"), by and through their undersigned counsel, file this Original Complaint against Defendant BOSTON SCIENTIFIC CORPORATION ("Boston Scientific" or "Defendant") as follows:

I. THE PARTIES

2. UT is an agency of the State of Texas and is the assignee and owner of patents relating to drug-releasing biodegradable fibers used in the delivery of therapeutics, including U.S. Patent Nos. 6,596,296 (the "'296 Patent") and 7,033,603 (the "'603 Patent"). UT has its principal place of business at 201 West 7th Street, Austin, Texas 78701. For the avoidance of doubt, UT neither waives its sovereign immunity nor consents to any suit or proceeding filed separate from this action, including but not limited to any declaratory judgment action or *inter partes* review.

3. TissueGen is the developer of ELUTE® fiber and the exclusive licensee of the

'296 Patent and '603 Patent. ELUTE® fiber is a groundbreaking biodegradable fiber format for advanced drug delivery, nerve regeneration, and tissue engineering. TissueGen was established in 2000 by Dr. Kevin Nelson, while still faculty in Biomedical Engineering at The University of Texas at Arlington, following his research with Dr. George Smith at UT Southwestern Medical Center at Dallas. TissueGen is a Delaware corporation with a principal place of business at 2110 Research Row, Suite 330, Dallas, Texas 75235.

4. Defendant BOSTON SCIENTIFIC CORPORATION ("Boston Scientific") is a Delaware corporation with a principal place of business at 300 Boston Scientific Way, Marlborough, Massachusetts 01752 and may be served through its registered agent, Corporation Service Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701, or wherever else it may be found.

II. JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. UT is an arm of the State of Texas, and has sovereign immunity. *See* TEX. EDUC. CODE § 61.003; TEX. GOV'T CODE § 441.101(3); *Tegic Comm'ns, Corp. v. Board of Regents of Univ. of Tex. Sys.*, 458 F.3d 1335, 1344-45 (Fed. Cir. 2006); *Xechem Int'l, Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 382 F.3d 1324, 1327-28 (Fed. Cir. 2004); *Northern Ins. Co. of N.Y. v. Chatham Cty., Ga.*, 547 U.S. 189, 193 (2006).

7. Venue is proper in the Western District of Texas because UT has sovereign immunity and this Court has personal jurisdiction over Defendant.

8. This Court has personal jurisdiction over Boston Scientific. Defendant has conducted and does conduct business within the State of Texas and the Western District of

Texas. Defendant is registered to conduct business in Texas with the Texas Secretary of State. Defendant has purposefully and voluntarily availed itself of the privileges of conducting business in the United States, the State of Texas, and the Western District of Texas by continuously and systematically placing goods into the stream of commerce through an established distribution channel with the expectation that they will be purchased by consumers in Texas and this District. Upon information and belief, Boston Scientific employs sales representatives in this District and/or has an agency relationship with sales representatives to promote sales of its products in this District.

9. Plaintiffs' causes of action arise directly from Defendant's business contacts and other activities in the State of Texas and this District. Upon information and belief, Defendant has committed acts of infringement in this District giving rise to this action and does business in this District, making sales and/or providing service and support for its customers, in this District. Defendant purposefully and voluntarily sold one or more of its infringing products with the expectation that they would be purchased by consumers in this District. These infringing products have been and continue to be purchased by consumers in this District. Defendant has committed acts of patent infringement within the United States, the State of Texas, and the Western District of Texas.

10. Venue is proper in the Western District of Texas because UT is an arm of the State of Texas, has the same sovereign immunity as the State of Texas, it would offend the dignity of the State to require it to pursue persons who have harmed the State outside the territory of Texas, and the State of Texas cannot be compelled to respond to any counterclaims, whether compulsory or not, outside its territory due to the Eleventh Amendment.

III. TISSUEGEN'S FOUNDATION

11. In the late 1990s, TissueGen's founder Dr. Kevin D. Nelson, while still faculty in Biomedical Engineering at The University of Texas at Arlington, was inspired to investigate delivering drugs directly from an extruded fiber while working to develop biodegradable vascular stents and microspheres for delivering non-toxic drugs to the inner ear.

12. Dr. Nelson's early work was followed by collaborations with Dr. George Smith at UT Southwestern Medical Center at Dallas, a leading researcher working on peripheral nerve regeneration, as well as Dr. Nadir Alikacem at the Callier Center, Texas Woman's University.

13. Working in peripheral nerve regeneration, Dr. Nelson and Dr. Smith showed fascicle formation in regenerated nerves with the aid of fibers, convincing Dr. Nelson that the fiber-based drug delivery technology had commercial viability.

14. The peripheral nerve regeneration work was the culmination of a long line of extremely successful experiments that demonstrated the benefit of drug delivery fibers in numerous applications.

15. With Dr. Alikacem, for example, Dr. Nelson demonstrated the ability to load a small pharmaceutical agent into a fiber to help stem the blindness that results from diabetes.

16. In 2000, Dr. Nelson embarked upon the path to commercialization by founding TissueGen, Inc. Dr. Nelson's work led to several issued patents, ultimately assigned to UT and licensed exclusively to TissueGen, including the '296 Patent and the '603 Patent.

17. Following relentless development efforts spanning more than a decade,

TissueGen has brought the scientific promise of implantable drug delivery via biodegradable fibers to commercial reality.

18. In 2013, TissueGen commercially released ELUTE® fiber, a groundbreaking biodegradable fiber format for advanced drug delivery, nerve regeneration, and tissue engineering.

19. ELUTE® fiber may directly replace standard fibers used in medical devices, including, but not limited to, biodegradable textiles currently on the market, and provide significantly improved clinical outcomes by delivering therapeutic agents directly at the site of the implant.

20. By delivering therapeutic agents including, but not limited to, pharmaceuticals and growth factors at the topical application or implant site, ELUTE® fiber may enable medical devices, including but not limited to cardiovascular stents, to aid the body's healing and regenerative processes.

IV. COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,596,296 B1

21. Plaintiffs repeat and re-allege every allegation of the prior paragraphs as though set forth fully herein.

22. On July 22, 2003, U.S. Patent No. 6,596,296 B1 (the "'296 Patent")—titled "Drug Releasing Biodegradable Fiber Implant"—was duly and legally issued by the United States Patent and Trademark Office to Board of Regents, The University of Texas System, as assignee of named inventors Kevin D. Nelson, Andres A. Romero-Sanchez, George M. Smith, Nadir Alikacem, Delia Radulescu, Paula Waggoner, and Zhibing Hu. A true and correct copy of the '296 Patent is attached hereto as **Exhibit A**.

23. UT is the owner of all right, title, and interest in and to the '296 Patent and has granted TissueGen an exclusive license "to manufacture, have manufactured, use, have

used, and/or Sell or have Sold" products including inventions and discoveries covered by the '296 Patent and "to otherwise exploit" UT's rights in information or discoveries covered by the '296 Patent.

24. The '296 Patent is directed to useful and novel compositions that provide for three-dimensional matrices for in vitro and in vivo use comprised of biodegradable polymer fibers capable of the controlled delivery of therapeutic agents.

25. Each claim of the '296 Patent is valid and enforceable and enjoys a statutory presumption of validity separate, apart, and in addition to the statutory presumption of validity enjoyed by every other of its claims. 35 U.S.C. § 282.

26. Upon information and belief, Defendant has been, and is currently, directly and/or indirectly infringing one or more claims of the '296 Patent in violation of 35 U.S.C. § 271, including as stated below.

27. Upon information and belief, Defendant has directly infringed, literally and/or under the doctrine of equivalents, and will continue to directly infringe claims of the '296 Patent by making, using, selling, offering to sell, and/or importing into the United States products that embody or practice the apparatus and/or method covered by one or more claims of the '296 Patent, including but not limited to the following products: Defendant's SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ Catheter), including the following products: H7493926008220, H7493926012220, H7493926016220, H7493926020220, H7493926024220, H7493926028220, H7493926032220, H7493926038220, H7493926008250, H7493926012250, H7493926016250, H7493926020250, H7493926024250, H7493926028250, H7493926032250, H7493926038250, H7493926008270,

H7493926012270, H7493926016270, H7493926020270, H7493926024270, H7493926028270, H7493926032270, H7493926038270, H7493926008300, H7493926012300, H7493926016300, H7493926020300, H7493926024300, H7493926028300, H7493926032300, H7493926038300, H7493926008350, H7493926012350, H7493926016350, H7493926020350, H7493926024350, H7493926028350, H7493926032350, H7493926038350, H7493926008400, H7493926012400, H7493926016400, H7493926020400, H7493926024400, H7493926028400, H7493926032400, H7493926038400 and any other products offered and/or sold under the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ Catheter) name (the "Monorail™ Catheter Products"); Defendant's SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Over-The-Wire), including the following products: H7493926108220, H7493926112220, H7493926116220, H7493926120220, H7493926124220, H7493926128220, H7493926132220, H7493926138220, H7493926108250, H7493926112250, H7493926116250, H7493926120250, H7493926124250, H7493926128250, H7493926132250, H7493926138250, H7493926108270, H7493926112270, H7493926116270, H7493926120270, H7493926124270, H7493926128270, H7493926132270, H7493926138270, H7493926108300, H7493926112300, H7493926116300, H7493926120300, H7493926124300, H7493926128300, H7493926132300, H7493926138300, H7493926108350, H7493926112350, H7493926116350, H7493926120350, H7493926124350, H7493926128350, H7493926132350, H7493926138350, H7493926108400, H7493926112400, H7493926116400, H7493926120400, H7493926124400,

H7493926128400, H7493926132400, H7493926138400 and any other products offered and/or sold under the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Over-the-Wire Catheter) name (the "SYNERGY™ Over-The-Wire Products"); and Defendant's products within the scope of FDA PMA Number P150003 (the "P150003 Products") (collectively, the "'296 Accused Products").

28. On information and belief, Defendant indirectly infringes the '296 Patent by inducing others to infringe one or more claims of the '296 Patent through sale and/or use of the '296 Accused Products. On information and belief, at least as a result of the filing of this action, Defendant is aware of the '296 Patent; is aware that its actions with regards to distributors, resellers, and/or end users of the '296 Accused Products would induce infringement; and despite such awareness will continue to take active steps—such as creating and disseminating the '296 Accused Products and product manuals, instructions, promotional and marketing materials, and/or technical materials to distributors, resellers, and end users—encouraging others to infringe the '296 Patent with the specific intent to induce such infringement.

29. Plaintiffs adopt, and incorporate by reference, as if fully stated herein, the attached claim chart for claim 1 of the '296 Patent, which is attached hereto as **Exhibit B**. The claim chart describes and demonstrates how Defendant infringes the '296 Patent. In addition, Plaintiffs allege that Defendant infringes one or more additional claims of the '296 Patent in a similar manner.

A. MONORAIL™ CATHETER PRODUCTS

30. At least one of the Monorail™ Catheter Products includes a biodegradable polymer fiber. For example, at least one of the Monorail™ Catheter Products is composed of bioabsorbable polymer.

31. The biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products comprises a first phase and a second phase. For example, the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products comprises polymer structure and structure containing pharmacological agents.

32. The first phase and the second phase comprising the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products are immiscible. For example, the polymer structure and the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products are immiscible.

33. The second phase comprising the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products includes at least one therapeutic agent. For example, at least one therapeutic agent (e.g., everolimus) is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products.

34. The second phase comprising the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products is derived from an aqueous solution, a hydrogel, or a polymer.

35. The therapeutic agent included in the second phase comprising the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products is a drug, a protein, an enzyme, a growth factor, an immunomodulator, a compound promoting angiogenesis, a compound inhibiting angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a pro-coagulation agent, a chemotactic agent, an agent to promote apoptosis, an agent to inhibit apoptosis, or a

mitogenic agent. For example, one or more antimicrobial agents are included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products.

36. The biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products is a single polymer, a co-polymer, or a mixture of polymers.

37. The biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products is a single polymer, a co-polymer, or a mixture of polymers selected from the group consisting of polypeptides, polydepsipeptides, nylon copolyamides, aliphatic polyesters, polydihydropyrans, polyphosphazenes, poly(ortho ester), poly(cyano acrylates), polyanhydride, modified polysaccharides and modified proteins.

38. The biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products includes aliphatic polyesters selected from the group consisting of poly(glycolic acid), poly(lactic acid), poly(alkylene succinates) poly(hydroxybutyrate), poly(butylene diglycolate), poly(epsilon-caprolactone) and copolymers, blends and mixtures thereof.

39. The therapeutic agent included the biodegradable polymer fiber included in at least one of the Monorail™ Catheter Products is released over time from said fiber.

B. SYNERGY™ OVER-THE-WIRE PRODUCTS

40. At least one of the SYNERGY™ Over-The-Wire Products includes a biodegradable polymer fiber. For example, at least one of the SYNERGY™ Over-The-Wire Products is composed of bioabsorbable polymer.

41. The biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products comprises a first phase and a second phase. For example, the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire

Products comprises polymer structure and structure containing pharmacological agents.

42. The first phase and the second phase comprising the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products are immiscible. For example, the polymer structure and the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products are immiscible.

43. The second phase comprising the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products includes at least one therapeutic agent. For example, at least one therapeutic agent (e.g., everolimus) is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products.

44. The second phase comprising the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products is derived from an aqueous solution, a hydrogel, or a polymer.

45. The therapeutic agent included in the second phase comprising the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products is a drug, a protein, an enzyme, a growth factor, an immunomodulator, a compound promoting angiogenesis, a compound inhibiting angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a pro-coagulation agent, a chemotactic agent, an agent to promote apoptosis, an agent to inhibit apoptosis, or a mitogenic agent. For example, one or more antimicrobial agents are included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products.

46. The biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products is a single polymer, a co-polymer, or a mixture of polymers.

47. The biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products is a single polymer, a co-polymer, or a mixture of polymers selected from the group consisting of polypeptides, polydepsipeptides, nylon copolyamides, aliphatic polyesters, polydihydropyrans, polyphosphazenes, poly(ortho ester), poly(cyano acrylates), polyanhydride, modified polysaccharides and modified proteins.

48. The biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products includes aliphatic polyesters selected from the group consisting of poly(glycolic acid), poly(lactic acid), poly(alkylene succinates) poly(hydroxybutyrate), poly(butylene diglycolate), poly(epsilon-caprolactone) and copolymers, blends and mixtures thereof.

49. The therapeutic agent included the biodegradable polymer fiber included in at least one of the SYNERGY™ Over-The-Wire Products is released over time from said fiber.

C. P150003 PRODUCTS

50. At least one of the P150003 Products includes a biodegradable polymer fiber. For example, at least one of the P150003 Products is composed of bioabsorbable polymer.

51. The biodegradable polymer fiber included in at least one of the P150003 Products comprises a first phase and a second phase. For example, the biodegradable polymer fiber included in at least one of the P150003 Products comprises polymer structure and structure containing pharmacological agents.

52. The first phase and the second phase comprising the biodegradable polymer fiber included in at least one of the P150003 Products are immiscible. For example, the polymer structure and the structure containing pharmacological agents comprising the

biodegradable polymer fiber included in at least one of the P150003 Products are immiscible.

53. The second phase comprising the biodegradable polymer fiber included in at least one of the P150003 Products includes at least one therapeutic agent. For example, at least one therapeutic agent (e.g., everolimus) is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the P150003 Products.

54. The second phase comprising the biodegradable polymer fiber included in at least one of the P150003 Products is derived from an aqueous solution, a hydrogel, or a polymer.

55. The therapeutic agent included in the second phase comprising the biodegradable polymer fiber included in at least one of the P150003 Products is a drug, a protein, an enzyme, a growth factor, an immunomodulator, a compound promoting angiogenesis, a compound inhibiting angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a pro-coagulation agent, a chemotactic agent, an agent to promote apoptosis, an agent to inhibit apoptosis, or a mitogenic agent. For example, one or more antimicrobial agents are included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the P150003 Products.

56. The biodegradable polymer fiber included in at least one of the P150003 Products is a single polymer, a co-polymer, or a mixture of polymers.

57. The biodegradable polymer fiber included in at least one of the P150003 Products is a single polymer, a co-polymer, or a mixture of polymers selected from the

group consisting of polypeptides, polydepsipeptides, nylon copolyamides, aliphatic polyesters, polydihydropyrans, polyphosphazenes, poly(ortho ester), poly(cyano acrylates), polyanhydride, modified polysaccharides and modified proteins.

58. The biodegradable polymer fiber included in at least one of the P150003 Products includes aliphatic polyesters selected from the group consisting of poly(glycolic acid), poly(lactic acid), poly(alkylene succinates) poly(hydroxybutyrate), poly(butylene diglycolate), poly(epsilon-caprolactone) and copolymers, blends and mixtures thereof.

59. The therapeutic agent included the biodegradable polymer fiber included in at least one of the P150003 Products is released over time from said fiber.

60. Defendant's acts of infringement have caused and will continue to cause substantial and irreparable damage to Plaintiffs.

61. As a result of Defendant's infringement of the '296 Patent, Plaintiffs have been damaged. Plaintiffs are, therefore, entitled to damages pursuant to 35 U.S.C. § 284 in an amount that presently cannot be pled but that will be determined at trial.

V. COUNT II: INFRINGEMENT OF U.S. PATENT NO. 7,033,603 B2

62. Plaintiffs repeat and re-allege each and every allegation of the prior paragraphs as though set forth fully herein.

63. On April 25, 2006, U.S. Patent No. 7,033,603 B2 (the "'603 Patent")—titled "Drug Releasing Biodegradable Fiber for Delivery of Therapeutics"—was duly and legally issued by the United States Patent and Trademark Office on April 25, 2006 to Board of Regents, The University of Texas System, as assignee of named inventors Kevin D. Nelson and Brent B. Crow. A true and correct copy of the '603 Patent is attached hereto as **Exhibit C**.

64. The Board is the owner of all right, title, and interest in and to the '603 Patent

and has granted TissueGen an exclusive license "to manufacture, have manufactured, use, have used, and/or Sell or have Sold" products including inventions and discoveries covered by the '603 Patent and "to otherwise exploit" the Board's rights in information or discoveries covered by the '603 Patent.

65. The '603 Patent is directed to useful and novel compositions that provide for three-dimensional matrices for in vitro and in vivo use comprised of biodegradable polymer fibers capable of the controlled delivery of therapeutic agents.

66. Each and every claim of the '603 Patent is valid and enforceable and enjoys a statutory presumption of validity separate, apart, and in addition to the statutory presumption of validity enjoyed by every other of its claims. 35 U.S.C. § 282.

67. Upon information and belief, Defendant has been, and is currently, directly and/or indirectly infringing one or more claims of the '603 Patent in violation of 35 U.S.C. § 271, including as stated below.

68. Upon information and belief, Defendant has directly infringed, literally and/or under the doctrine of equivalents, and will continue to directly infringe claims of the '603 Patent by making, using, selling, offering to sell, and/or importing into the United States products that embody or practice the apparatus and/or method covered by one or more claims of the '603 Patent, including but not limited to the following products: Defendant's SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ Catheter), including the following products: H7493926008220, H7493926012220, H7493926016220, H7493926020220, H7493926024220, H7493926028220, H7493926032220, H7493926038220, H7493926008250, H7493926012250, H7493926016250, H7493926020250, H7493926024250,

H7493926028250, H7493926032250, H7493926038250, H7493926008270, H7493926012270, H7493926016270, H7493926020270, H7493926024270, H7493926028270, H7493926032270, H7493926038270, H7493926008300, H7493926012300, H7493926016300, H7493926020300, H7493926024300, H7493926028300, H7493926032300, H7493926038300, H7493926008350, H7493926012350, H7493926016350, H7493926020350, H7493926024350, H7493926028350, H7493926032350, H7493926038350, H7493926008400, H7493926012400, H7493926016400, H7493926020400, H7493926024400, H7493926028400, H7493926032400, H7493926038400 and any other products offered and/or sold under the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ Catheter) name (the "Monorail™ Catheter Products"); Defendant's SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Over-The-Wire), including the following products: H7493926108220, H7493926112220, H7493926116220, H7493926120220, H7493926124220, H7493926128220, H7493926132220, H7493926138220, H7493926108250, H7493926112250, H7493926116250, H7493926120250, H7493926124250, H7493926128250, H7493926132250, H7493926138250, H7493926108270, H7493926112270, H7493926116270, H7493926120270, H7493926124270, H7493926128270, H7493926132270, H7493926138270, H7493926108300, H7493926112300, H7493926116300, H7493926120300, H7493926124300, H7493926128300, H7493926132300, H7493926138300, H7493926108350, H7493926112350, H7493926116350, H7493926120350, H7493926124350, H7493926128350, H7493926132350, H7493926138350, H7493926108400,

H7493926112400, H7493926116400, H7493926120400, H7493926124400, H7493926128400, H7493926132400, H7493926138400 and any other products offered and/or sold under the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Over-the-Wire Catheter) name (the "SYNERGY™ Over-The-Wire Products"); and Defendant's products within the scope of FDA PMA Number P150003 (the "P150003 Products") (collectively, the "'603 Accused Products").

69. On information and belief, Defendant indirectly infringes the '603 Patent by inducing others to infringe one or more claims of the '603 Patent through sale and/or use of the '603 Accused Products. On information and belief, at least as a result of the filing of this action, Defendant is aware of the '603 Patent; is aware that its actions with regards to distributors, resellers, and/or end users of the '603 Accused Products would induce infringement; and despite such awareness will continue to take active steps—such as, creating and disseminating the '603 Accused Products and product manuals, instructions, promotional and marketing materials, and/or technical materials to distributors, resellers, and end users—encouraging others to infringe the '603 Patent with the specific intent to induce such infringement.

70. Plaintiffs adopt, and incorporate by reference, as if fully stated herein, the attached claim chart for claim 19 of the '603 Patent, which is attached hereto as **Exhibit D**. The claim chart describes and demonstrates how Defendant infringes the '603 Patent. In addition, Plaintiffs allege that Defendant infringes one or more additional claims of the '603 Patent in a similar manner.

A. MONORAIL™ CATHETER PRODUCTS

71. At least one of the Monorail™ Catheter Products includes a drug delivery composition.

72. The drug delivery composition included in at least one of the Monorail™ Catheter Products includes at least one fiber.

73. The fiber comprising the drug delivery composition included in at least one of the Monorail™ Catheter Products includes an emulsion consisting of a hydrogel or a colloidal system with at least two phases, one of which phases forms a continuous three-dimensional network that acts as an elastic solid.

B. SYNERGY™ OVER-THE-WIRE PRODUCTS

74. At least one of the SYNERGY™ Over-The-Wire Products includes a drug delivery composition.

75. The drug delivery composition included in at least one of the SYNERGY™ Over-The-Wire Products includes at least one fiber.

76. The fiber comprising the drug delivery composition included in at least one of the SYNERGY™ Over-The-Wire Products includes an emulsion consisting of a hydrogel or a colloidal system with at least two phases, one of which phases forms a continuous three-dimensional network that acts as an elastic solid.

C. P150003 PRODUCTS

77. At least one of the P150003 Products includes a drug delivery composition.

78. The drug delivery composition included in at least one of the P150003 Products includes at least one fiber.

79. The fiber comprising the drug delivery composition included in at least one of the P150003 Products includes an emulsion consisting of a hydrogel or a colloidal system with at least two phases, one of which phases forms a continuous three-dimensional network that acts as an elastic solid.

80. Defendant's acts of infringement have caused and will continue to cause

substantial and irreparable damage to Plaintiffs.

81. As a result of Defendant's infringement of the '603 Patent, Plaintiffs have been damaged. Plaintiffs are, therefore, entitled to damages pursuant to 35 U.S.C. § 284 in an amount that presently cannot be pled but that will be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray for entry of judgment against Defendant as follows:

A. A judgment that Defendant has infringed and continues to infringe the '296 Patent and the '603 Patent, directly and/or indirectly, as alleged herein;

B. That Defendant provides to Plaintiffs an accounting of all gains, profits, and advantages derived by Defendant's infringement of the '296 Patent and the '603 Patent, and that Plaintiffs be awarded damages adequate to compensate them for the wrongful infringement by Defendant, in accordance with 35 U.S.C. § 284;

C. That Plaintiffs be awarded any other supplemental damages and interest on all damages, including, but not limited to, attorney fees available under 35 U.S.C. § 285;

D. That the Court permanently enjoin Defendant and all those in privity with Defendant from making, having made, selling, offering for sale, distributing, and/or using products that infringe the '296 Patent and the '603 Patent, including the '296 Accused Products and the '603 Accused Products, in the United States; and

E. That Plaintiffs be awarded such other and further relief and all remedies available at law.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues triable to a jury.

Dated: November 20, 2017

Respectfully submitted,

/s/ Alfonso G. Chan

Michael W. Shore (Texas 18294915)
mshore@shorechan.com
Alfonso G. Chan (Texas 24012408)
achan@shorechan.com
Chijioke E. Offor (Texas 24065840)
coffor@shorechan.com

SHORE CHAN DEPUMPO LLP
901 Main Street, Suite 3300
Dallas, Texas 75202
Telephone (214) 593-9110
Facsimile (214) 593-9111

COUNSEL FOR PLAINTIFFS BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM and TISSUEGEN, INC.